TERUMO

K073474

MAR - 5 2008

SECTION 5
510(k) Summary

Submitter Information:

This submission was prepared in November 2007 by:

Garry A. Courtney, MBA, RAC
Sr. Regulatory Affairs Specialist
Regulatory Affairs
Terumo Corporation/Terumo Cardiovascular
125 Blue Ball Road
Elkton, MD 21921
Telephone: 1-800-283-7866, Ext. 7420

This submission was prepared for:

Terumo Corporation (Ashitaka Factory)
Manufacturer/Sterilizer
150 Maimaigi-cho, Fujinomiya City
Shizuoka Pref.
Japan 418-0015
Registration #9681834

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Capiox® Circuit Connectors	Adaptor, Stopcock, Manifold or Fitting (Code: DTL)	Fitting

Predicate Device:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

- Terumo Circuit Connectors – K041697 – Cleared by FDA on August 11, 2004.

Intended Use:

The Capiox Circuit Connectors are intended to be used to interconnect tubing and other devices in an extra-corporeal circuit during cardiopulmonary bypass procedures. The devices can be used in procedures lasting up to 6 hours in duration.

Principles of Operation and Technology:

The Capiox Circuit Connectors that are the subject of this premarket notification perform by providing a connection between the devices within a bypass circuit, effectively establishing a conduit between the devices for the flow of blood and other extra-corporeal fluids.

Design and Materials:

The connectors that are the subject of this premarket notification are of various designs (quick-connection and rotary-style) – each of which provides for the flow of blood and extra-corporeal fluids through the bypass circuit. Each of the connectors is made from polycarbonate and includes a silicone rubber O-ring for seal maintenance. Similarly, the predicate connectors are also quick-connect style connectors and include a silicone rubber O-ring for seal maintenance.

The materials of construction for both the proposed and predicate devices are commonly used in medical devices and are not considered exotic in nature.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- 6-Hour Circulation Test - (Comparative v. predicate device)
- Dimensional Analysis - (Attribute Evaluation / Not compared to predicate)
- Structural Integrity / Leakage Testing - (Attribute Evaluation / Not compared to predicate)
- Tubing Connection Strength - (Attribute Evaluation / Not compared to predicate)

Substantial Equivalence Comparison:
The information presented in this section depicts a comparison between the subject of this 510(k) submission, the Capiox Circuit Connectors, and the predicate Terumo Connectors.

- ***Comparison of Intended Use:***
  The Capiox Circuit Connectors and the predicate Terumo Connectors have the same intended uses:

  > Both the proposed and predicate connectors are intended to be used to interconnect tubing and other devices in an extra-corporeal circuit during cardiopulmonary bypass procedures. The devices can be used in procedures lasting up to 6 hours in duration.

- ***Comparison of Duration of Use:***
  The Capiox Circuit Connectors and the predicate devices can be used in procedures lasting up to 6 hours.

- ***Comparison of Labeling***:
  Both the Capiox Circuit Connector and the predicate Terumo devices are offered with Instructions for Use and other product labeling as required by regulation. The Instructions for Use for the Capiox Circuit Connectors are presented in the Appendices of this submission; the Instructions for Use for the predicate devices are also presented in the Appendices of this submission.

- ***Comparison of Principles of Operation & Technology:***
  Both the Capiox Circuit Connectors and the predicate Terumo Connectors utilize the exact same technologies and principles of operation:

  Each device operates by providing a mechanical connection between and among the devices that comprise the extra-corporeal circuit. When the connectors are sufficiently placed into position, they provide the necessary interface between circuit components to establish a conduit for the flow of fluids.

- ***Comparison of Design:***
  The design of the Terumo Circuit Connectors and the predicate Terumo Connectors are essentially the same. The respective designs differ only in the physical dimensions of the devices – with such differences being product attributes that do not impact performance or patient safety.

- ***Comparison of Materials:***
  The Capiox Circuit Connectors and the predicate Terumo Connectors use similar materials that are commonly used in many blood-contacting medical devices and whose safety and biocompatibility characteristics are well-recognized and well-documented. Each of the connectors is comprised of a polycarbonate housing and includes a silicone rubber O-ring.

  One difference in materials that does exist between the Terumo Circuit Connectors and the predicate Terumo Connectors is that the new connectors contain a surface coating on the blood-contacting surfaces. The predicate connectors do not include this coating. The coating (trade marked as X-Coating™) is a non-heparin based coating that reduces the adhesion of platelets to the device as blood flows through the circuit). The coating has been used in many Terumo devices since June 2000 and it's safety as a medical device coating is well recognized. The use of the coating does not introduce any new issues of safety or product effectiveness.

  Section 15 of this application further details the biocompatibility aspects of the new device.

- ***Comparison of Performance:***
  The Capiox Circuit Connectors exhibited performance that is deemed to be *substantially equivalent* to the performance of the predicate devices. This determination is based upon the results of the following tests:

  - 6-Hour Circulation Test
  - Dimensional Analysis
  - Structural Integrity / Leakage Testing
  - Tubing Connection Strength

  Each of the above-indicated tests is reported in detail in Section 18 of this submission.

Conclusion:
In summary, Terumo deems the Capiox Circuit Connectors as *substantially equivalent* to the predicate Terumo Connectors with respect to intended use, duration of use, design, materials, principles of operation, performance and specifications. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.

Substantial Equivalence Statement:
The Capiox Circuit Connectors and the predicate devices are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.
- Terumo maintains biocompatibility studies for all blood-contacting materials as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials are considered to be biocompatible.
- The polymer coating material that is applied to the blood-contacting surfaces of the devices have been evaluated in an *in-vivo* animal study for previous devices submitted to FDA for marketing clearance. No adverse conditions have been noted.

Conclusion:

In summary, the Capiox Circuit Connectors are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate connector devices identified in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2008

Terumo Cardiovascular Systems Corp.
c/o Mr. Garry Courtney
Senior Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K073474
Capiox Circuit® Connectors
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adapter, stopcock, manifold or fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: December 4, 2007
Received: December 11, 2007

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TERUMO

SECTION 4
Indications for Use

510(k) Number (if known): K073474

Device Name: **CAPIOX® Circuit Connectors**

Indications For Use:

The Capiox Circuit Connectors are intended to be used to interconnect tubing and other devices in an extra-corporeal circuit during cardiopulmonary bypass procedures. The devices can be used in procedures lasting up to 6 hours in duration.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahoney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073474